Fuel Up: Onderzoek naar het herstel van burn-out door meer inzicht in positieve emoties.

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The following objectives are examined in a randomized controlled trial whether: 1. The use of Psymate feedback on (work-related) situations leads to an increase in Positive Affect (PA), a decrease in Negative Affect (NA) and more effective person-...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26760

Bron
Nationaal Trial Register

Verkorte titel
Fuel Up study

Aandoening

burn out PsyMate positive affect negative affect UBOS UWES feedback bevlogenheid work engagement daily life experience sampling

Ondersteuning

Primaire sponsor: J. van Os, head of department Psychiatry & Neuropsychology, University of Maastricht, the Netherlands
Overige ondersteuning: J. van Os, head of department Psychiatry & Neuropsychology, University of Maastricht, the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Main outcome measures are pre and post intervention changes in PA, NA and person-tailored strategies as measured with the PsyMate are the main outcome measures for this aim. Multilevel regression analyses are used;
2. Pre – post intervention change in burn out symptomatology as measured with the UBOS questionnaire and Work Engagement as measured with the UWES questionnaire at the end of the intervention, using a t-test;
3. Follow up measures (after 12 and 24 weeks) are changes in burn out symptomatology as measured with the UBOS questionnaire and Work Engagement as measured with the UWES questionnaire.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

We hypothesize that momentary assessment technology (PsyMate) during cognitive behavioural treatment (CBT) for participants suffering from burn out will enrich therapy by stimulating positive affect (PA) and Work Engagement (WE) through feedback about feelings, cognitions and environment. We hypothesize that this addition enhances therapeutic efficacy by reducing symptoms and relapse rate.

Objectives:

Does feedback on daily life experiences with the PsyMate during CBT affect basal levels and responses of Negative Affect (NA) and PA in relation to daily life experiences and work appraisals?

Does an increase in PA as a result of the PsyMate feedback lead to a better treatment response (immediate reductions of burn out symptoms, immediate increase of Work Engagement level) than CBT alone?

Does the use of PsyMate feedback result in a decreased relapse risk at follow up?

Is feedback on continuous monitoring with the PsyMate during CBT cost-effective?

Do changes in daily life experiences (both in the experimental and the control condition) predict outcome at follow up (in terms of relapse risk and symptoms)?

Can this study contribute to the collection of a unique sample with the combination of momentary assessment data and molecular genetic information in order to elucidate mechanisms of psychopathology?

Study design:

Randomized controlled trial (RCT) with three groups (1 experimental group with 30 subjects and 2 control groups with each 15 subjects). The experimental group receives a continuous PsyMate assessment (3 days of PsyMate measurements during 6 weeks with weekly feedback to both patient and therapist during CBT. The first control group receives CBT with PsyMate but no feedback. The second control group receives only CBT. All groups receive a 5-day pre- and post PsyMate assessment.

Study population:

A sample of patients (n=60), seeking therapy for burn out at Prima and LavOri, departments of RIAGG Maastricht.

Intervention:

The PsyMate is a recently developed wearable interactive palmtop suitable for the Experienced Sampling Method (ESM) to study subjects in their daily life. The intervention group receives feedback on PsyMate measurements on their experience of PA, NA and appraisals of daily (work) context.

Main study parameters/endpoints:

The rate of change in PA and work activity appraisals measured with the PsyMate, and the change in burn out symptomatology, work engagement respectively measured with the UBOS (Utrecht Burn Out Scale) and the UWES (Utrecht Work Engagement Scale). The cost effectiveness of the PsyMate intervention is measured with the TiC-P, PRODISQ and EQ-5D.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

There are no health risks associated with participation. Personal benefits for the subjects are (i) an increase in insight and control over recovery mechanisms, and (ii) the standard

treatment can be adapted to the individual needs with the use of feedback. Burden for the patients is investment of time.

Doel van het onderzoek

The following objectives are examined in a randomized controlled trial whether:

1. The use of Psymate feedback on (work-related) situations leads to an increase in Positive Affect (PA), a decrease in Negative Affect (NA) and more effective person-tailored strategies in work-related contexts;

2. Person-tailored feedback on appraisals of work-related activities, NA and PA, (as measured with the PsyMate) during CBT has an additional effect in terms of immediate decrease of burn out symptomatology (as measured with the UBOS) and increase of the work engagement level (as measured with the UWES);

3. Person-tailored feedback on daily life (work) situations (as measured with the PsyMate) reduces symptoms and relapse risk for burn out (as measured with the UBOS) and a higher level of work engagement (as measured with the UWES) at follow up;

4. Additional person-tailored feedback on relevant dynamic daily life emotional experiences in work-related contexts (as measured with the PsyMate) during CBT is cost-effective. The cost effectiveness of the PsyMate intervention is measured with the questionnaire for costs associated with psychiatric illness(TiC-P), a modular questionnaire on productivity and disease for economic evaluation studies (PRODISQ) and EuroQoL-5D (EQ-5D);

5. Changes in daily life experiences such as increasing levels of PA (both in the experimental and the control condition) predict outcome at follow up (in terms of relapse risk, symptoms and level of work engagement);

6. The study contributes to a larger data collection of momentary assessment data and genetic information because the sample size for DNA research needs to be larger than the current study. With the use of the DNA data from this study it will be examined how genetic differences are associated with prospectively measured momentary emotional experiences in interplay with daily life contexts. Momentary positive emotions, as measured with the PsyMate, reduces the moderating effect of genetic risk for stress sensitivity.

Onderzoeksopzet

Week 1:

1. Quickscan / intake;

2. Questionnaires.

Week 2:

1. Questionnaires;

2. Instruction for assessment on daily life experiences;

3. Assessment on daily life experiences.

Week 4-10:

1. Assessment on daily life experiences (dependant on condition);

2. Feedback on daily life experiences (dependant on condition);

3. Questionnaires.

Week 11- end of therapy:

1. Continuation therapy (CBT), if applicable;

2. End of therapy: Questionnaires and 1 week assessment on daily life experiences.

12 weeks after end of therapy:

1. Follow up session 1;

2. Questionnaires.

24 weeks after end of therapy:

1. Follow up sessie 1;

2. Questionnaires.

Onderzoeksproduct en/of interventie

The experimental group receives 5-day pre- and post PsyMate assesments and continuous Psymate assessment (each week 3-days PsyMate measurement during a 6- weeks period) with feedback on Positive Affect (PA) (to both patient and therapist) during treatment as

usual (TAU= Cognitive Behavioural Therapy) with the aim of stimulating PA and Work Engagement.
Patients in the experimental arm receive PsyMate feedback after each PsyMate intervention week. This sums up to a total of 6 feedback moments. The PsyMate feedback will be given written, and graphically (in clear pie charts and bar graphs) to both patient and therapist, showing emotional responses to daily life activities, events, social and work situations and how these daily life situations relate to momentary affective responses of the participant.

The control group (n= 30) is divided into 2 subarms:

1. Control group number 1 (n=15) receives 5-day pre- and post PsyMate assessments but no additional intervention during TAU;

2. Control group number 2 (n=15) receives 5-day pre- and post PsyMate assessments and continuous PsyMate assessment (each week 3 days PsyMate measurement during a 6 week period) without feedback. We don’t expect a placebo effect of the PsyMate feedback. People receive the feedback of the PsyMate during a regular session with their therapist, so they receive no higher level of attention. Thereby it’s common in CBT that people receive ‘homework’, like registration of activities, mood, thoughts. Partly the PsyMate covers this, so in the experimental group there will be less need to registrate beside the use of the PsyMate. In order to monitor subtle differences in intensity and a-specific effects, we divided the control group in two, as stated above. This gives the possibility to monitor these issues.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. 18-65 years;

2. Meeting the criteria of burn out (`Exhaustion+1' criterion) as defined by Brenninkmeyer and Van Yperen;

3. Adequate vision;

4. Sufficient Dutch language skills.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Diagnosis of non-affective psychosis (e.g. schizophrenia), schizoaffective disorder (current) or a bipolar disorder. Because burn out is not known as a psychiatric syndrome in a current psychiatric classification system, the Mini International Neuropsychiatric Interview (MINI) is used to determine the psychiatric classification.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-03-2012

Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-03-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 35867
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3134
NTR-old	NTR3334
CCMO	NL35703.068.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35867

Resultaten

Samenvatting resultaten
N/A